



July 20, 2004

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mead C. Killion, Ph.D., Sc.D.
Etymotic Research, Inc.
61 Martin Lane
Elk Grove Village, IL 60007

Re: Reclassification Petition:
2004P-0037
TV-TIP Sound Amplifier

Dear Dr. Killion:

Introduction

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your January 14, 2004 petition for reclassification of the TV-TIP Sound Amplifier that is intended for use in amplifying sound for that part of the general population considered to have normal to marginal hearing loss who desire an additional boost in sound for occasional use in various listening environments. You suggest that this device is not substantially equivalent to any hearing aid currently legally marketed because it is intended for over-the-counter (OTC) use and therefore, the device is in class III (premarket approval) by operation of section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)(1)) (the Act). You request that FDA reclassify this device into class I (general controls) and designate it as exempt from the premarket notification requirements. You also believe that the TV-TIP Sound Amplifier does not need to be subject to the labeling and conditions for sale regulations for hearing aids in Title 21 of the Code of Federal Regulations (CFR) 801.420 and 801.421 (21 CFR 801.420 and 801.421).

Identification of the Device

You identify this generic type of device for which you are seeking reclassification, as follows:

The TV-TIP Sound Amplifier is a high-fidelity in-the-ear amplification device designed to amplify sound for that part of the general population considered to have normal to marginal hearing loss who desire an additional boost in sound for occasional use in various listening environments. The device would be available over-the-counter (OTC) at retail outlets.

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Regulatory Authorities

In accordance with section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution prior to May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976 (the amendments)), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with new section 513(f)(2) of the act (21 U.S.C. 360c(f)(2)), as amended by the FDAMA; or (3) FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously marketed devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

Reclassification Petition

As you know, on January 22, 2004, FDA filed your petition requesting reclassification of TV-TIP Sound Amplifier from class III into class I. The petition was submitted under section 513(f)(3) of the act and 21 CFR 860.134 of the agency's regulations. You assert that in accordance with section 513(f)(1) of the act, the TV-TIP Sound Amplifier was automatically classified into class III because the TV-TIP Sound Amplifier was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and had not been found substantially equivalent to a device placed in commercial distribution after May 28, 1976, which was subsequently reclassified into class II or class I. In order to reclassify the TV-TIP Sound Amplifier intended to amplify sound for persons with marginal hearing loss into class I, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of safety and effectiveness of the device for its intended use.

After review of the information submitted in the petition, for the reasons discussed below, FDA has determined that the TV-TIP Sound Amplifier cannot be regulated as a class I device exempt from the premarket notification requirements without being a restricted device subject to the labeling and conditions for sale requirements of §§ 801.420 and 801.421.

Classification of the Hearing Aids

Pursuant to Section 520(e) of the Medical Device Amendments to the Act, FDA is authorized to restrict the sale, distribution, or use of a device, if, because of its potentiality for harmful effect or the collateral measures necessary to its use, there cannot otherwise be reasonable assurance of its

safety and effectiveness. Restrictions may include limiting a device to sale, distribution, or use only on oral or written authorization by a licensed practitioner or upon other conditions specified by regulation.

Hearing aids are restricted devices under 21 CFR sections 801.420 and 801.421. These regulations were enacted on February 15, 1977 and promulgated pursuant to section 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 (h)). Under the terms of the current regulations, before the sale of a hearing aid, the hearing aid dispenser must obtain from each prospective purchaser a written statement signed by a licensed physician stating that the physician has evaluated the patient's hearing loss and that the patient may be considered a candidate for a hearing aid. The physician must have performed the medical evaluation within 6 months prior to the sale of the hearing aid. If the prospective hearing aid user is 18 years of age or older, the hearing aid dispenser may afford the prospective user an opportunity to waive the medical evaluation requirement provided that the hearing aid dispenser informs the prospective user that the exercise of the waiver is not in the user's best health interest and does not in any way actively encourage the prospective user to waive the medical evaluation.

You state that the TV-TIP Sound Amplifier is very similar in design and performance to the air conduction hearing aid. FDA has classified air conduction hearing aids in class I and has exempted them from the premarket notification (21 CFR 874.3300(b)(1)). The history of the classification of hearing aids is as follows:

- In the Federal Register of January 22, 1982 (47 FR 3280), FDA proposed to classify hearing aids into class II.
- In the Federal Register of November 6, 1986 (51 FR 40378), FDA issued a final rule classifying air conduction hearing aids into class I and bone conduction hearing aids into class II.
- In the Federal Register of January 14, 2000 (65 FR 2296), FDA issued a final rule exempting air conduction hearing aids from the premarket notification requirements.
- In the classification process, FDA stated clearly that the labeling and conditions for sale of §§ 801.420 and 801.421 were an integral part of the regulatory scheme that persuaded FDA that classification of the air conduction hearing aid into class I would provide reasonable assurance of the safety and effectiveness of the device.

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Analysis of Petition

On August 7, 2003, you submitted a citizen petition [Docket No. 2003P-0362] that requested that FDA create a new over-the-counter hearing aid classification that would grant OTC status to certain “one size fits most” hearing aid devices. On February 13, 2004, FDA issued a response denying that petition (enclosed). FDA believes that the reasons that it stated for denying that petition apply equally to this reclassification petition and is incorporating that response by reference in this response.

In the February 13, 2004 response to your citizen petition, FDA stated that it is concerned that if prospective purchasers of hearing aids are not examined by a physician prior to using the hearing aid, “red flag” ear conditions will go undiagnosed and unevaluated. Red flag ear conditions are signs, symptoms, or audiometric findings that a licensed physician must evaluate to determine whether a person experiencing hearing impairment is an appropriate candidate for a hearing aid, or whether his impairments may be medically or surgically treated. Examples of red flag ear conditions include: visible congenital or traumatic deformity of the ear; history of active drainage or bleeding from the ear within the previous six months; sudden or rapidly progressive hearing loss in either ear within the previous six months; air-bone gap of 15 decibels or greater at 500 Hz, 1,000 Hz, and 2,000 Hz; asymmetric hearing loss; acute or chronic dizziness; visible evidence of excessive ear wax (cerumen) or a foreign body in the ear canal; and ongoing pain or discomfort in the ear.

In your reclassification petition, you state: “Extensive research has indicated that this device is safe for the intended population.” You do not include or further describe this extensive research.

In the section of your reclassification petition addressing risks to health, you list as a risk “complications as the result of self-prescribe [sic] if the following conditions exist: congenital deformity of the ear, history of active drainage, history of sudden hearing loss, significant cerumen accumulation, foreign body in ear canal, pain or discomfort, [and] vertigo.” You state that the risk of these complications can be mitigated by labeling. You also state that the cause of this hazard would be that the patient does not heed warnings in labeling.

Your list of risks to health does not include all of the “red flag” conditions identified above. Nor have you shown that these “red flag” conditions are not relevant to the TV-TIP Sound Amplifier. Furthermore, your petition does not state how patients will self-diagnose all of the “red flag” conditions. Your submission does not adequately address FDA’s concern expressed in the February 13, 2004 petition response that “elimination of the existing medical examination and waiver requirements may result in significant delays in the diagnosis and management of medically and surgically treatable causes of hearing loss.”

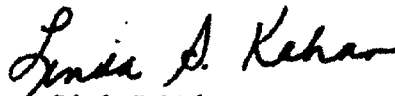
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Conclusion

After reviewing your petition, for the reasons stated above, FDA is unable to conclude that classifying the TV-TIP Sound Amplifier in class I and exempting the device from the premarket notification requirements without applying the restrictions of §§ 801.420 and 801.421 would provide reasonable assurance of the safety and effectiveness of the device. Therefore, FDA is denying your petition.

If you have any questions about this response, please contact Eric Mann at (301) 594-2018.

Sincerely yours,



Linda S. Kahan
Deputy Director
Center for Devices and
Radiological Health